

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of: **Garvey et al**

Application No.: **Not Yet Assigned**

Filed: **October 28, 2003**

For: **Phosphodiesterase Inhibitors and Nitric Oxide Donors,  
Compositions and Methods of Use**

Docket No: 102258.287US4

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

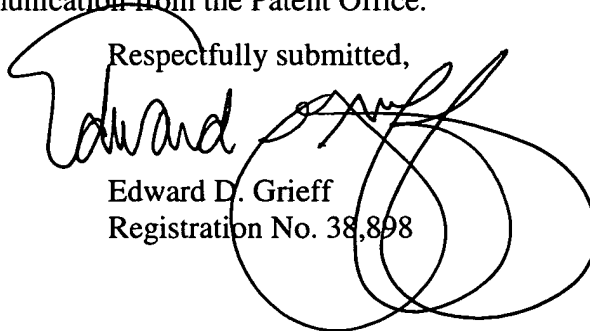
A copy of each of the cited references is not submitted herewith since they were filed and/or cited in one of the applications to which the present application claims priority. 37 CFR § 1.98(d).

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being submitted before the mailing date of a first office action on the merits or a notice of allowance. Accordingly, no fee is due.

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Patent Office.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'Edward D. Grieff', is written over the typed name and registration number.

Edward D. Grieff  
Registration No. 38,898

Date: October 28, 2003  
HALE AND DORR LLP  
1455 Pennsylvania Avenue, NW  
Washington, DC 20004  
Phone: (202) 942-8400

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<b>FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary) (37 CFR 1.98(b))	<b>ATTY DOCKET NO.</b> 102258.	<b>SERIAL NO.</b>
	<b>APPLICANT</b> GARVEY et al	
	<b>FILING DATE</b>	<b>GROUP</b>

## U.S. PATENT DOCUMENTS

EXAMINER INITIALS		PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		4	3	0	8	2	7	8	12/29/81	Schneider et al			
		5	1	9	6	4	2	6	03/23/93	Saccomano et al			
		5	2	2	3	5	0	4	06/29/93	Noverola et al			
		5	2	5	4	5	7	5	10/19/93	Pick et al			
		5	3	4	0	8	2	7	08/23/94	Beeley et al			
		5	4	2	6	1	0	7	06/20/95	Bell et al			07/23/93
		5	4	9	1	1	4	7	02/13/96	Boyd et al			02/13/95
		5	5	4	5	6	4	7	08/13/96	Tanaka et al			03/06/95
		5	6	4	5	8	3	9	07/08/97	Chobanian et al			06/07/95
		5	6	1	8	8	1	4	04/08/97	Heckel et al			08/02/94
		5	5	8	3	1	0	1	12/10/96	Stamler et al			07/15/94
		5	3	8	0	7	5	8	01/10/95	Stamler et al			
		5	4	3	8	0	6	0	08/01/95	Miyazaki et al			07/12/94
		5	1	7	1	2	1	7	12/15/92	March et al			
		4	9	6	3	5	4	1	10/16/90	Brooks et al			

## FOREIGN PATENT OR PUBLISHED PATENT APPLICATION

		DOCUMENT NUMBER							PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
		9	5	0	1	3	3	8	01/12/95	PCT				

## OTHER DOCUMENTS (Including Author, Title, Date, Relevant pages, Place of Publication)

		Boolell et al, <i>International Journal of Impotence Research</i> , 8:47-52 (1996).
		Krane et al, <i>New England Journal of Medicine</i> , 321(24):1648-1659 (1989).
		Trigo-Rocha et al, <i>Neurourol. Urodyn.</i> , 13(1):71-80 (1994).
		Sparwasser et al, <i>J. Urol.</i> , 152:6, Pt. 1, pages 2159-2163 (1994).

EXAMINER

DATE CONSIDERED

**EXAMINER:** Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Modified) PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)  
(37 CFR 1.98(b))

ATTY DOCKET NO.  
102258

SERIAL NO.

APPLICANT  
GARVEY et al

FILING DATE

GROUP  
1611

U.S. PATENT DOCUMENTS

EXAMINER INITIALS	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5 8 7 7 2 1 6	03/02/99	Place et al			10/28/97
	5 7 6 7 1 6 0	06/16/98	Kaesemeyer			08/05/96
	5 6 9 8 5 8 9	12/16/97	Allen			01/30/96
	5 5 4 3 4 3 0	08/06/96	Kaesemeyer			10/05/94
	5 1 9 0 9 6 7	03/02/93	Riley			
	5 6 4 6 1 8 1	07/08/97	Fung et al			05/02/95
	5 5 6 5 4 6 6	10/15/96	Gioco et al			08/09/94
	5 4 9 2 9 1 1	02/20/96	Stief			11/17/93
	5 4 3 9 9 3 8	08/08/95	Snyder et al			04/07/93

FOREIGN PATENT OR PUBLISHED PATENT APPLICATION

DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION YES NO
9 8 1 9 6 7 2	05/14/98	PCT			
2 5 4 7 5 0 1	12/21/84	France (Abstract)			

OTHER DOCUMENTS (Including Author, Title, Date, Relevant pages, Place of Publication)

	Terrett et al, <i>Bioorg. Med. Chem. Lett.</i> , 6(15):1819-1824 (1996).
	Park et al, <i>Biochem. Biophys. Res. Commun.</i> , 249(3):612-617 (1998).
	Mathers et al, <i>European Urology</i> , 35(suppl 2):67 (abstract 266) (1999).
	Zorgniotti et al, <i>Int. J. Impotence Res.</i> , 6:33-36 (1994).

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<b>FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use several sheets if necessary) (37 CFR 1.98(b))	<b>ATTY DOCKET NO.</b> 102258.287	<b>SERIAL NO.</b>
	<b>APPLICANT</b> Garvey et al	
	<b>FILING DATE</b>	<b>GROUP</b>

**U.S. PATENT DOCUMENTS**

EXAMINER INITIALS		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5 6 1 4 6 2 7	03/25/97	Takase et al			
		5 7 1 6 9 9 3	02/10/98	Ozaki et al			
		5 8 4 9 7 4 1	12/15/98	Watanabe et al			
		5 8 5 9 0 0 6	01/12/99	Daugan			
		5 8 6 9 5 1 6	02/09/99	Arlt et al			

**FOREIGN PATENT OR PUBLISHED PATENT APPLICATION**

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
		9 7 0 3 6 7 5	02/06/97	WIPO				
		9 7 4 3 2 8 7	11/20/97	WIPO				
		9 8 1 7 6 6 8	04/30/98	WIPO				
		9 7 0 3 9 8 5	02/06/97	WIPO				
		9 8 4 9 1 6 6	11/05/98	WIPO				
		9 8 5 2 5 6 9	11/26/98	WIPO				
		9 9 2 1 5 5 8	05/06/99	WIPO				
		9 9 2 1 5 6 2	05/06/99	WIPO				
		9 9 2 2 7 3 1	05/14/99	WIPO				
		9 9 3 0 6 9 7	06/24/99	WIPO				
		9 3 0 7 1 4 9 4 15 93		WIPO				

**OTHER DOCUMENTS (Including Author, Title, Date, Relevant pages, Place of Publication)**


<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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**EXAMINER:** Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**Under the Paperwork Reduction Act of 1995, no pers**

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete If Known</b>	
				Application Number	
				Filing Date	
				First Named Inventor	Garvey, David S.
				Group Art Unit	1624
				Examiner Name	R. Raymond
Sheet	4	of	6	Attorney Docket Number	102258.287

[illegible]

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		EP	0 352 960		Smith Kline French	01-31-1990		
		WO	96/25184		Gen Hospital Corp	08-22-1996		
		EP	0 463 756		Pfizer Ltd.	01-02-1992		
		WO	95/26725		Noack et al	10-12-1995		
		WO	97/34871		Garvey et al	09-25-1997		
		WO	95/09636		Lawson et al	04-13-1995		
		EP	0 506 194		AKZO N.V.	09-30-1992		
		EP	0 442 204		Smith Kline	08-21-1991		
		EP	0 252 721		Ortho Pharma.	01-12-1988		
		WO	97/39760		Adams et al	10-30-1997		

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments or the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

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PTO/SB/08B (10-86)  
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Trademark Office: U.S. DEPARTMENT OF COMMERCE  
nation unless it contains a valid OMB control number.

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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	
		Filing Date	
		First Named Inventor	Garvey, David S.
		Group Art Unit	1624
		Examiner Name	R. Raymond
		Attorney Docket Number	102258.287
Sheet	5 of 6		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Chemical Abstracts, Vol. 120, No. 1, Abstract No. 5451d (1994).	
		Martel et al, Drugs of the Future, 22(2):138-143 (1997).	
		Boolell et al, British Journal of Urology, 78(2):257-261 (1996).	
		Chemical Abstracts, Vol. 116, No. 1, Abstract No. 4477 (January 6, 1992).	
		Chemical Abstracts, Vol. 125, No. 15, Abstract No. 191382 (October 7, 1996).	
		Chemical Abstracts, Vol. 123, No. 1, Abstract No. 574 (July 3, 1995).	
		Chemical Abstracts, Vol. 120, No. 25, Abstract No. 315630 (June 20, 1994).	
		Chemical Abstracts, Vol. 121, No. 7, Abstract No. 73410 (August 15, 1994).	
		Patnaik et al, Indian Journal of Pharmacology, 11(2):139-142 (1979).	
		Agarwal et al, Indian Journal of Chemistry, 29B:80-84 (1990).	
		Saxena et al, QSAR Strategies Des. Bioact. Compd., Proc. Eur. Symp. Quant. Struct. Act. Relat., 5 <sup>th</sup> (1985), Meeting Date 1984, pages 361-365.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

**Complete if Known**

(use as many sheets as necessary)

Sheet 6

6

of

6

**Application Number****Filing Dat**

**First Named Inventor**

Garvey .

**Group Art Unit**

**Examiner Name**

Attorney Docket Number

102258.287 US3

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner  
Signature**

Date \_\_\_\_\_

**Considered**

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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